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by Kay Bulen
Signature

Kay Bulen
Printed Name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sajid Ahmed

Serial No.: 09/757,015

Filed: January 8, 2001

For: SYSTEM AND METHOD FOR DECISION MAKING

Art Unit: 2122

Examiner: to be assigned

Docket No.: 53296-2

Date: 02 January 2002

Assistant Commissioner for Patents
Washington, DC 20231

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Technology Center 2100

PETITION TO MAKE SPECIAL (37 CFR 1.102(d))

Sir or Madam:

Applicant hereby submits a PETITION TO MAKE SPECIAL, under 37 C.F.R. 1.102, along with a supporting AFFIDAVIT. A check in the amount of \$130 is enclosed to cover the petition fee. Please charge any additional fees due and credit any overpayment to Deposit Account No. 04-0258.

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DIRECTOR OFFICE
TECHNOLOGY CENTER 2100

REMARKS

There is an urgent public health need to develop and commercialize rapid, reliable and cost effective systems to diagnose anthrax and other **bio-terrorism**-related afflictions. The instant invention (*see* Appendix A, attached hereto) provides such a system.

BIO-TERRORISM

The tragic events of 11 September 2001 have created a heightened state of public anxiety, and have provided an urgent need to enhance the capacity and responsiveness of the U.S. public health infrastructure in view of the real threat of widespread bio-terrorism.

Generally doctors are still struggling to effectively educate themselves and develop fast and efficient methods to distinguish between symptoms of bio-terrorism agents and other diseases. Health officials fear that doctors and emergency rooms will be overwhelmed by people with the flu fearing that they have anthrax, because many of the early symptoms of anthrax are similar to influenza¹. Thus, a scenario involving a bio-terrorist anthrax attack alongside an influenza outbreak raises the specter of significant bio-terrorist-inflicted mortality, because limited supplies of antibiotics effective against anthrax may be unnecessarily depleted or exhausted by fearful influenza patients and physicians.

Even an aggressive program of flu vaccination may not preclude catastrophe where such generalized vaccination does not sufficiently precede an anthrax attack, or where the vaccine is only mildly effective at preventing the flu, as is sometimes the case.

Additionally, there is currently no supply of anthrax vaccine to prophylactically vaccinate the U.S. population, nor will there be in the foreseeable future.

Likewise, the signs and symptoms of small pox, botulism, plague, etc. will be difficult to distinguish from those conditions with similar symptoms.

PRIOR ART DIAGNOSTIC EXPERT SYSTEMS

Prior art expert systems are significantly limited as applied to the diagnosis of complex medical phenomena, such as anthrax or other bio-terrorism agents. The task of medical diagnosis, as an expert system, comprises three basic steps: detection; classification; and recommendation. Detection refers to the step in which symptoms associated with one or more specific illnesses or conditions are first recognized. Classification is the process of designating or naming the condition, for instance, categorizing the condition into a known diagnostic group. Recommendation is the step in which the physician prescribes a course of treatment for the condition.

Various problems are often encountered when performing one or more of these diagnoses steps in a typical clinical setting for decision-making:

Consistency is problematic. On any given day, a physician may be fatigued or under stress. She or he may be inexperienced in a particular medical specialty. Identical

¹ Fever, cough, headache, vomiting, chills, weakness, abdominal pain, etc.

clinical data and parameter values monitored for one patient may be interpreted differently by two physicians, due to their different medical training, experience level, stress level or other factors.

Transference/Interpretation problems exist. One physician's mental rules in the diagnosis of a medical condition may be hard to describe, and hence, difficult to transfer from one physician to another. These mental rules may also be difficult to explain to a patient if he asks how the physician arrived at the diagnosis, or even to document reasoning for use by other physicians.

Non-linearity factors are often present. When the relationships between the monitored values and the patient's condition are complex and not well understood, conventional (e.g., linear, statistical) models are often inaccurate and thus not sufficient or reliable. Therefore, diagnostic technology using more complex nonlinear models is clearly preferable and often necessary.

These and other problems which are related, at least in part, to human error and limitations in the area of medical diagnosis can be addressed successfully using computer-aided diagnostic tools. Conventional computer-aided medical diagnosis is based on statistical data analysis. More advanced diagnostic tools are based on artificial intelligence ("AI") technology which generally involves expert systems, fuzzy logic, artificial neural networks and various combinations thereof. The advent of effective commercially available software and hardware

tools of these types has greatly broadened the base of potential and realized medical applications. Still, none of the presently available medical diagnostic tools is capable of adequately addressing the problems discussed above.

There are only a few existing expert system applications that employ some facet of fuzzy logic in complex systems, such as medical diagnosis. This is primarily because they have inherent limitations when applied to imprecise fields. Such current applications have inherent problems relating to the classification of patient states and medical decision-making. Existing medical applications using expert systems or fuzzy logic include MYCINTM, EMYCINTM, PUFFTM, and OMERONTM. MYCINTM is used for diagnosing blood and meningitis infections. MYCINTM took over 20 man-years to make and was 65 percent accurate compared to human physician accuracy of 42.5 to 62.5 percent. EMYCINTM is an empty shell inference engine used in other areas. PUFFTM is used for diagnosing pulmonary problems. Omron is a Japanese company that developed a health management system, where over 500 fuzzy rules track and evaluate an employee's health and fitness. These existing applications are limited to small areas within medicine and are not realized commercially. In addition, intelligent, accurate medical applications are non-existent on the Internet.

THE INSTANT INVENTION

Petitioner's invention relates to information systems theories and expert systems theories. The invention provides a process, apparatus and method for decision making, based on

emulation of the human decision-making process using expert-generated primary bias values. A primary bias value, as used in this invention, associates a particular alternative possibility of a possibility set with a particular query, and reflects the expert's conception of the relative degree of predictive value of the query for the particular alternative relative to other alternatives in the possibility set. Specifically, the present invention provides a process, apparatus and method for providing a medical diagnosis or medical self-assessment.

Petitioner's system minimizes the above-identified flaws inherent to human decision making including poor framing, recency effects, primacy effects, poor probability estimation, overconfidence, escalation phenomena, association bias and "groupthink." The system emulates the human decision-making process, but is not based on the application of statistics, probability or certainty factors, and accordingly does not require large statistical data bases that are expensive to maintain and update. Essentially, the system ranks possibilities according to likelihood based on values provided by human experts (*e.g.*, Infectious Disease Specialists), and draws from the expert's intuition, cognition and experience. The system determines the nature of particular medical conditions with great accuracy, and provides a diagnosis in a way that identifies and catalogues all factors that were significant in the process of making the diagnosis. The system is flexible, inexpensive and can be made widely available via the Internet or other computer device such as hand-held PDA. The system provides for self-evaluation, or diagnostic assistance to physicians or hospitals.

Petitioner's invention can be used to inform and educate the public on anthrax and other

bio-terrorism agents, and can prevent unnecessary and potentially dangerous² usage of antibiotics in attempts to treat misdiagnosed cases of anthrax, especially in flu season. Expedited review of petitioner's claimed subject matter will help address national health needs, and aid in countering paranoia related to bio-terrorism.

The Special Program Examiner is encouraged to review the following URL, which provides a useful demonstration of the Petitioner's subject matter. Log-in using the "enter" button, and select a body region by 'clicking' on Da Vinci's "Vitruvian man."

<http://www.igotpain.com>

User ID: petition

Password: bioterrorism

Related News Articles

Finally, to facilitate consideration of the present PETITION, Petitioner attaches the following Appendices summarizing recent and relevant Associated Press and Reuters articles:

Appendix B, p.1, para 6 and 7; RE: responsiveness and capacity of the U.S. public health infrastructure;

Appendix C, p.2, para 3 and 4; RE: no supply of anthrax vaccine for prophylactic vaccination

Appendix D, p. 1, para 7 and 8; RE: physicians struggling to educate themselves and develop effective diagnostic skills;

Appendix D, p.2, para 10-13, Dr. Meryl Nass; RE: urgency placed on early effective diagnosis, and a need to rapidly leverage the knowledge of a limited number of anthrax experts;

Appendix E, p.2, para 2; RE: potential for inclusion of key demographic information to enable an effective diagnostic capability;

² Such as harmful side-effects, and the evolution of antibiotic-resistant strains of anthrax.

Appendix F, p.2, para 2; RE: potential of emergency rooms being overwhelmed by people with the flu, fearing that they have anthrax;

Appendix G, p.1, para 3; RE: potential for non-FDA approved antibiotics as a safety net;

Appendix H, p.1, para 3; RE: potential for rapid depletion of limited supplies of antibiotics and precious vaccines effective against anthrax;

Appendix H, p.2, para 8 and 9; RE: potential for unnecessary and potentially dangerous usage of antibiotics in attempts to treat misdiagnosed cases of anthrax, especially in flu seasons;

Appendix I, p.2, para 6; RE: limited efficacy of flu vaccine at precluding the active flu strain;

Appendix I, p.2, para 4; RE: potential for derivative hysteria arising among those who mistakenly rush to conclude that they have anthrax, because they are presenting with flu-like symptoms despite the fact that they were previously vaccinated for flu.

Respectfully submitted,

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5 Jan. 2, 2002 Kay Bulen by Kay Bulen
Date Signature Printed Name

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Applicant: Sajid Ahmed
10 Serial No.: 09/757,015
Filed: January 8, 2001
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Art Unit: 2122
Examiner: to be assigned
15 Docket No.: 53296-2
Date: December 17, 2001

Assistant Commissioner for Patents
Washington, DC 20231

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20 **AFFIDAVIT OF DR. JOEL A. STRENG**
(IN SUPPORT OF PETITION TO MAKE SPECIAL UNDER 37 CFR § 1.102(d))

Sir or Madam:

I, Dr. Joel A. Streng, being duly sworn, say:

1. I am an internationally recognized infectious disease specialist and am presently
25 employed as a Consultant of Infectious Disease at Foothills Infectious Disease in Covina,
California. I also hold the position of Clinical Professor of Pediatrics and Infectious Disease at
Los Angeles County—University of Southern California Medical Center, Los Angeles,
California.

2. I received an M.D. degree from the University of Cincinnati in 1971. I completed an internship and residency in Pediatrics at Los Angeles County--University of Southern California Medical Center in 1976; and from 1972-74 I served as First Lieutenant at Public Health Service for developing areas. I completed a Fellowship in Adult and Pediatric Infectious Disease in 1977. I passed the Pediatric Board in 1977, the Infectious Disease Board in 1994 (first time given) and recertification in 2001.

3. I am an author or co-author of more than five peer-reviewed research articles and I am a member of a number of scientific and medical societies. I have received a number of prizes and awards for achievement in Pediatrics and Infectious Disease.

4. I have read and understood the attached PETITION TO MAKE SPECIAL, for which I served as consultant. I have also reviewed and understood the nature of the claimed subject matter of the above-identified pending patent application. I understand that the premise of the PETITION is that the claimed subject matter will help address urgent national health needs, and aid in countering bioterrorism. I make this Affidavit to provide my expert opinion as to whether this premise is, in fact, justifiable such that the subject matter should be considered by the Assistant Commissioner for accelerated prosecution at the USPTO.

5. It is my opinion, based on my information and belief, that the representations of the PETITION with respect to current emergency health care capacity, and vaccine and antibiotic availability and efficacy, are fair and accurate. I make no opinion as to the absolute truth or accuracy of the "Related News Articles" consisting of various recent Associated Press or Reuters articles attached to the PETITION (*i.e.*, Appendices B-I), but find them generally relevant and consistent with the premise of the PETITION.

6. It is my opinion that there is an urgent public health need to develop and commercialize rapid, reliable and cost effective systems to diagnose anthrax and other bioterrorism-related afflictions, because a scenario involving a bio-terrorist attack (*e.g.*, anthrax) alongside an influenza outbreak raises the specter of significant bio-terrorist-inflicted mortality.

7. It is also my opinion that the instant invention provides such a system, whereby the knowledge and experience of a limited number of key experts can be rapidly and efficiently leveraged to help minimize bio-terrorist inflicted mortality.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

10 Joel A. Streng MD
Joel A. Streng

State of California)
) ss.:
15 County of Los Angeles)

20 On this 20th day of December, 2001, before me, a Notary Public in and for the State and County aforesaid, personally appeared Joel A. Streng, to me known and known to me to be the person of that name, who signed and sealed the foregoing instrument, and he acknowledged the same to be his free act and deed.

Susan R.W. Carter
Notary Public

Commission expires 3/20/01

